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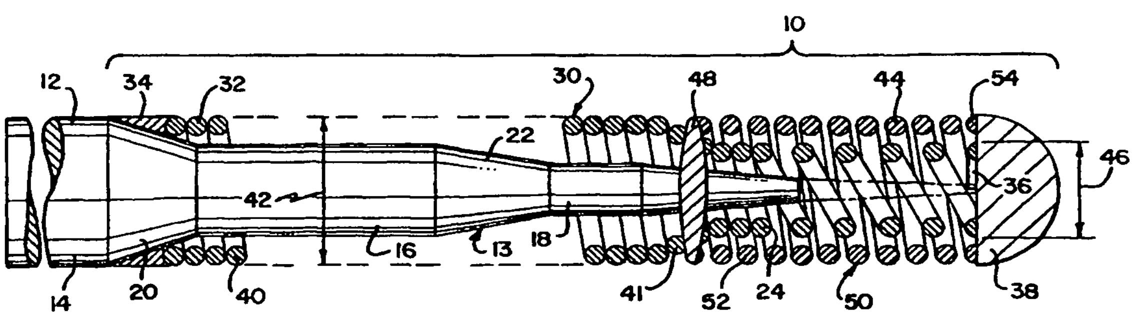

(57) Abstract

A guidewire having a flexible distal end region that permits axisymmetric steering and forming, said guidewire comprising: a core wire having a main body and a flexible distal end at said flexible distal end region of said guidewire; a flexible first coil coupled to said distal end of said core wire, said first coil having a proximal section with a first outer diameter and a distal section with a second outer diameter smaller than said first outer diameter; and a flexible second coil coupled to said first coil and positioned substantially concentrically over said distal section of said first coil; wherein said second coil is formed from a formable material capable of reaching a stress value above its yield point such that said second coil maintains a desired bend imparted thereto to thereby impart a bend to said distal end of said guidewire.

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VASCULAR GUIDEWIRE WITH AXISYMMETRIC STEERING AND SPRING FORMING ELEMENTS

BACKGROUND OF THE INVENTION

The present invention relates to a steerable vascular guidewire having an improved distal end region. More particularly, the present invention relates to a vascular guidewire having a highly flexible, yet formable end region that permits axisymmetric steering such that 360° steerability is possible within the patient. Additionally, the present invention provides an improved radiopaque distal end region that is more flexible than prior art radiopaque tips, and more easily visualized.

Steerable vascular guidewires are commonly used to access coronary or other human vasculature to allow the use of various devices within the vasculature, as is necessary in percutaneous transluminal coronary angioplasty. In order to facilitate steering within the vasculature, the distal-most region of the guidewire is more flexible than the proximal portion of the guidewire. Because the vessels into which vascular guidewires are inserted tend to be small, tortuous, and delicate, the distal-most region of the guidewire should further be designed as an atraumatic tip, i.e., the distal-most region should be extremely flexible to be able to maneuver within the patient's vasculature without damaging the blood vessel walls, yet strong enough to withstand bending without breaking.

Typically, steerable vascular guidewires have a flexible central wire core that is tapered at its distal end. Thus, the core wire is more flexible at its distal end to permit increased flexibility of the distal region of the guidewire. Guidewires typically also include a flexible coil (main body spring) bonded to the distal-most, tapered end of the core wire to form an extremely flexible distal region of the guidewire. The flexible coil may be partially radiopaque so that the position of the guidewire can be monitored fluoroscopically during the procedure. Alternatively, an additional

radiopaque coil may be provided. A safety wire, coupled to both the flexible coil and to the core wire, may also be provided to prevent over-expansion and uncoiling of the coil in response to tensile forces applied to the tip. It is desirable to prevent overexpansion because overexpanded coils at the end of the guidewire do not have an appropriate or desired "feel" for the physician forming the guidewire end. However, safety wires typically do not have circular cross-sections, and therefore may interfere with uniform bendability of the guidewire end region in any plane of the distal region of the guidewire. In particular, safety wires typically are only bendable in a single plane and, once bent in that plane, cannot be bent in another plane. Thus, further steering of the guidewire is limited to bending in the same plane such that axisymmetric steering (steering in any plane through the guidewire) is not possible.

The distal end region of the guidewire should provide a blunt, minimum-trauma, distal end that permits the guidewire to be maneuvered in particularly tortuous vessels without digging into plaque deposits or puncturing the vessel walls. It is also desirable to provide an easily formable end region that permits the physician or user to bend the tip as desired at the time of use. The end region should be sufficiently formable to maintain the desired bend, yet not so formable as to cause the bent region to take on a permanent set when the wire is bent over itself during use in the body. Typically, formability of the guidewire distal end region is permitted by providing a forming ribbon or wire within the main body spring of the guidewire. The forming ribbon is made of a suitable material that permits bending and has some memory so that the material maintains the bend imparted thereto. Prior art forming ribbons typically have a rectangular cross-section and therefore can only be formed in a single plane (i.e., the forming ribbon can only be bent towards or away from, i.e., perpendicular to the plane of, the wider of the flat side surfaces of the forming ribbon). Accordingly, prior art forming ribbons interfere with axisymmetric bending of the distal end region of the guidewire because the distal end region of the guidewire is constrained to bend with the forming ribbon and thus within a single plane. Additionally, because of the rectangular cross-section of the forming ribbon, the forming ribbon interferes with full (360°) rotation of the guidewire once the distal end of the guidewire is bent in the plane in which the forming ribbon is formed. This is because although the forming ribbon may bend with the flexible distal end of the guidewire, it can only bend in one plane, and, once bent in that plane, cannot be bent

in another plane. Thus, the distal end region may resist multiplane tortuousity, thereby losing the ability to advance further into the vasculature. As described above in connection with the safety wire, such limitations impose on the bending of an already bent guidewire, essentially prevent axisymmetric steering. The non-circular cross-section of the forming ribbon also does not smoothly transmit to the distal end of the guidewire torque applied to the proximal end of the guidewire to properly orient the formed tip. Thus, rotation of the guidewire may also cause the distal end region of the guidewire to exhibit unstable whipping upon release of torsional energy stored therein, or may cause the distal end region to move in an unpredictable and uncontrolled manner.

The provision of an additional coil to provide radiopacity at the distal tip of the guidewire, as described above, further complicates guidewire design considerations. Additional radiopaque wire coils must be sufficiently flexible so that the additional coil does not interfere with the flexibility of the distal end region. Moreover, the radiopacity must be selected such that the distal end region of the guidewire is easily detected, yet does not interfere with observation of the interior of the vasculature.

Summary Of The Invention

It is therefore an object of the present invention to provide a guidewire having a highly flexible yet formable distal end region that permits stable, axisymmetric steering.

It is a further object of the present invention to provide a guidewire having a radiopaque distal end region with improved visibility, such that visualization of the distal end region of the guidewire is facilitated yet the radiopaque distal end region does not interfere with visualization of the vascular area of interest.

It is yet another object of the present invention to provide a guidewire having an element in the distal end region that assures that the guidewire tip does not become detached from the rest of the guidewire, yet does not prevent axisymmetric steering of the distal end of the guidewire.

In accordance with these and other objects of the present invention, a guidewire is provided with a formable distal end region having increased flexibility and axisymmetric steering capability. The guidewire is formed with a core wire having a

tapered distal end to which two coaxially, concentrically arranged wire coils are coupled. The first coil provides the required increased flexibility at the distal end region of the guidewire, in a manner known in the art, and is known as the main body spring.

Preferably, the main body spring extends beyond the distal end of the core wire to provide greater flexibility to the distal end region of the guidewire than would be provided if the core wire were also present. The main body spring has a proximal section having a first outer diameter and a distal section having a second outer diameter smaller than the first outer diameter. Preferably, the pitch of the distal section is greater than the pitch of the proximal section. The distal section of the main body spring is inserted into a second, radiopaque forming coil, which has an outer diameter substantially equal to the first outer diameter of the main body spring, such that the composite structure has a substantially uniform outer diameter. The main body spring, positioned within the radiopaque forming coil, thus serves a dual function as a safety element which does not impair axisymmetric steering because of its coiled shape.

The second wire coil serves as a forming spring, because it is made of a formable material that permits the tip to be formed or bent as desired for the particular use of the guidewire. The material from which the forming element is generally stiffer than the material from which the main body spring is made. Thus, provision of a forming spring having a diameter larger than the main body spring in the same region allows greater flexibility in that region. The forming spring, because of its shape, permits axisymmetric steering and stable rotation of the curved tip through full (360°) rotation of the guidewire. Preferably, the forming spring is radiopaque and thus also serves to facilitate visualization of the guidewire tip during use. Thus, a radiopaque coil having a diameter greater than that of prior radiopaque coils may be provided for improved visualization. A reinforcement element may be provided to ensure that the distal end region of the guidewire is not overexpanded.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be readily apparent from the following detailed description of the invention, the scope of the invention being set out in the appended claims. The detailed description will be

better understood in conjunction with the accompanying drawings, wherein like reference characters represent like elements, as follows:

Fig. 1 is a cross-sectional view of a distal end region of a guidewire formed in accordance with the principles of the present invention; and

Fig. 2 is a cross-sectional view of a distal end region of a guidewire similar to that of Fig. 1 but with an element for preventing unintentional overexpansion of the tip.

Detailed Description Of The Invention

A distal end region 10 of a guidewire formed in accordance with the principles of the present invention to have increased flexibility in addition to formability is shown in Fig. 1. The guidewire is formed from a hardened core wire 12 that is relatively flexible and has a substantially round cross-section so that the wire can be guided within tortuous human vasculature. In order to provide a distal end region 10 of increased flexibility, core wire 12 is preferably tapered at its distal end 13. Typically, the tapering of core wire 12 is accomplished by forming successive barrel segments 14, 16, 18 alternating with successive tapers 20, 22, 24, the barrels having successively reduced diameters decreasing distally along the guidewire. Main barrel segment 14 forms the main body of core wire 12 and thus has the greatest length and diameter. Intermediate barrel segment 16 has a diameter smaller than that of main barrel 14 and extends from main barrel segment 14 via taper 20. Distal-most barrel segment 18 has a diameter smaller than that of intermediate barrel segment 16 and extends from intermediate barrel segment 16 via taper 22. Preferably, the distal free end of core wire 12 is formed as a tapered tip 24. The proximal end of core wire 12 may be hollow, if desired, for attachment of extension wires. The number and dimensions of the various barrel segments and tapers do not form a part of the present invention, and accordingly may be selected as desired. Additional barrel segments may be provided if desired.

Distal end region 10 is additionally provided with a main body spring 30 which is preferably formed from a metal alloy which is extremely flexible yet not easily breakable. Main body spring 30 is placed over the distal end 13 of core wire 12. Proximal end 32 of main body spring 30 is fixed to core wire 12 with a suitable bonding technique, such as welding, brazing or soldering. Preferably, proximal end

32 is joined to taper 20 by a braze joint 34 formed with an appropriate brazing material as known in the art. Distal end 36 of main body spring 30 is attached (or bonded) at its tip to rounded tip 38 of the guidewire in any desired manner known in the art. Preferably, distal end 36 of main body spring 30 extends distally beyond tapered tip 24 of core wire 12 to provide the guidewire with increased flexibility in its distal-most end. At a point near tapered tip 24 of core wire 12, the diameter of main body spring 30 is decreased and main body spring 30 is preferably also extended to increase its pitch. Accordingly, main body spring 30 has a proximal section 40 with a first outer diameter 42 and a distal section 44 having a second smaller outer diameter 46. Proximal section 40 gradually tapers into distal section 44 via a tapering section 41 of main body spring 30. Main body spring 30 is bonded at a second point adjacent the distal-most end of core wire 12 at joint 48. To provide some stability, main body spring 30 (preferably the tapering portion 41 between proximal section 40 and distal section 44) is bonded to tapered tip 24 of core wire 12. Joint 48 may be a braze joint or an adhesive joint, such as a UV cured adhesive joint. Distal section 44 of main body spring 30 preferably extends past tapered tip 24 such that the core wire is not positioned therein and therefore cannot affect the flexibility of distal section 44, thereby providing a distal-most guidewire end of increased flexibility. Smaller diameter distal sections 44 of main body spring 30, by extending between tip 24 of core wire 12 and tip 38 of the guidewire, serves a dual function of providing a flexible distal end section to the guidewire and also of providing the benefits typically provided by a safety ribbon, thereby permitting elimination of a safety ribbon in the present invention. Thus, a safety feature is provided without impeding axisymmetric steering of the distal end of the guidewire. However, it will be understood that tapered tip 24 may extend to distal tip 38 of the guidewire, if desired, as shown in phantom in Fig. 1. Because the cross-section of tapered tip 24 of core wire 12 is preferably substantially round, even if tip 24 extends to distal tip 38 of the guidewire, it would not interfere with axisymmetric bending and steering of the guidewire.

The forming element of prior art guidewires typically is in the form of a safety ribbon which serves the additional function of ensuring that the distal tip does not become detached from the main body of the guidewire. Instead of a safety ribbon, the distal end region 10 of the guidewire of the present invention includes a forming spring 50 positioned substantially concentrically over reduced diameter section 44 of

main body spring 30. Forming spring 50 may be wound clockwise or counterclockwise (either in the same direction as main body spring 30 or in the opposite direction) over distal section 44 of main body spring 30. Preferably, springs 30 and 50 are wound in opposite directions to reduce the chances of intermeshing when the coils of spring 50 spread apart. The proximal end 52 of forming spring 50 is bonded to main body spring 30 and core wire 12 at bond joint 48, and distal end 54 is bonded to rounded distal tip 38 of the guidewire (and thus is also bonded to distal end 34 of main body spring 30). The proximal end 52 may additionally or alternatively be captured by non-expanded turns of main body spring 30 (i.e., proximal end 52 of forming spring 50 may be screwed together with the distal end of proximal section 40 of main body spring 30). Forming spring 50 thus is configured to span distal end region 10 between the core wire bond at the distal end of core wire 12, and the rounded distal tip 38 of the guidewire. Because the forming element is in the form of a forming spring 30, and the only other elements at the distal end of the guidewire have substantially round cross-sections, axisymmetric bending and steering are possible.

Forming spring 50 is formed such that it is capable of maintaining the desired bend at the distal end of the guidewire, even if the other elements at the distal end (e.g., the main body spring 30) are not capable of maintaining a bend imparted thereto on their own. Thus, although main body spring 30 and core wire 12 may be bent, as well, they need not be capable of maintaining a bend imparted thereto because forming spring 50 is selected to maintain a bend securely enough to maintain the bend of main body spring 30 and core wire 12, even if these latter elements cannot maintain a bend. Accordingly, forming spring 50 is not only shaped and selected to permit axisymmetric bending and forming but also is selected to be capable of reaching a stress value above its yield point so that forming spring 50 takes on a permanent deformation to impart and maintain a bend in the distal end of the end guidewire.

Because distal end region 10 is extremely flexible and readily formable, it may be desirable to provide a reinforcement element to prevent unintentional overexpansion of the tip when the physician is forming the tip. A reinforcement element 60 may thus be provided in modified distal end region 110 shown in Fig. 2. Elements in Fig. 2 similar to elements in Fig. 1 are labelled with the same reference numeral increased by 100. Reinforcement element 60 is in the form of a ribbon bonded

to core wire 112 and extending distally beyond the tapered distal free end 124 of core wire 112. Preferably, like core wire 12, reinforcement element 60 has a substantially circular cross-section so that axisymmetric steering is possible. Instead of a ribbon, the reinforcement element may be formed from a thread or filament such as suture material, or any other non-rigid, flexible material that does not maintain a fixed shape, but does maintain its length to prevent overexpansion of springs 130, 150. As may be seen in Fig. 2, core wire 112 is tapered like core wire 12 of Fig. 1. Joint 148, which couples distal section 144 of main body spring 130, forming spring 150, and core wire 112, is preferably located at tapered distal free end 124.

Instead of providing a separate reinforcement element 60, it is also within the scope of the present invention to extend the distal end of core wire 112 to be coupled to the rounded distal tip 138 of the guidewire, such as shown in phantom in Fig. 2. It will be understood that the ribbon 60, or the extension of the distal end of core wire 112 is only provided for reinforcement and is not necessary for safety because the two coil elements 30, 50, or 130, 150 alone are sufficient to retain the tip of the guidewire on the remainder of the guidewire in case of catastrophic failure. As in the first described embodiment, because the cross-section of core wire 112 is substantially round, the extension of core wire 112 will not interfere with axisymmetric bending and steering of the guidewire.

Thus, in accordance with the principles of the present invention, both the formable spring and the expanded main body spring contribute to the flexibility of the distal end region 10, 110 of the guidewire of the present invention. Spring parameters such as wire diameter, material, pitch, and expanded length therefore must be selected to provide the desired flexibility.

The main body spring parameters, such as wire diameter, material, pitch, and expanded length are chosen to provide a proper flexibility contribution to the overall performance of distal end region 10, 110. Preferred values are as follows. The wire from which main body spring 30, 130 is formed is preferably a 304 stainless steel wire having a diameter between approximately 0.0005in (0.0127 mm) and 0.004in (0.0102cm), and optimally, approximately 0.002in (0.0508mm). MP35N (an aluminum metal-based alloy), or nitinol, or any other suitable material may be used instead. Proximal section 40, 140 of main body spring 30, 130 is preferably a closed coil having a first outer diameter 42 between approximately 0.010in (0.0254 cm) and

approximately 0.018in (0.046 cm), optimally, approximately 0.0138in (0.0351cm). The outer diameter 46 of distal section 44, 144 is reduced to approximately 0.009in (0.0229 cm) and the pitch is increased to approximately 0.0104in (0.0264 cm).

Preferably, the wire diameter of forming spring 50, 150 is selected such that the stress yield point of forming spring 50, 150 will be exceeded for a given forming radius so that forming spring 50, 150 may be formed or bent as desired and maintain the desired shape or bend during steering within human vasculature. For example, a wire having a diameter of between approximately 0.0005in (0.0127mm) and 0.004in (0.1016mm), and optimally approximately 0.002in (0.0508mm) is used. If the diameter is too small, forming spring 50, 150 won't yield and, therefore, the diameter selected must be large enough to permanently bend. The diameter is also selected based on a given range of bending radii typically used to achieve the desired steerability at the distal end of the guidewire. The selected forming spring wire diameter must be capable of maintaining a desired bend within a typical range of bending radii commonly used in bending guidewire distal ends. Preferably, forming spring 50, 150 is not a closed coil, but, rather has gaps between adjacent coil surfaces of the coil windings, for example of approximately 0.0084in (0.0213cm). The outer diameter of forming spring 50 is preferably the same as outer diameter 42 of proximal section 40, 140 of main body spring 30, 130 which, in turn, is preferably the same as the outer diameter of main section 14 of core wire 12, 112. Additionally, the outer diameter 56 of rounded tip 38, 138 is preferably the same as the outer diameter of forming spring 50, 150. Accordingly, the guidewire has a substantially uniform outer diameter.

Typically, tapered distal end 13 of core wire 12 is between about 30cm and 36cm, and optimally, 34cm, with the length of tapered tip 24 being between approximately 1cm and approximately 5cm, and optimally, 4.5cm. The length of main body spring 30 from proximal joint 34 to distal joint 48 (i.e., proximal section 40) is preferably between approximately 28cm and approximately 34cm, and optimally, 32cm. The distance between distal joint 48 and the distal surface of guidewire 38 (and thus, the approximate length of distal section 44 of main body spring 30 and forming spring 50) is preferably between approximately 1cm and approximately 4cm, and optimally, 2.7cm. Proximal end 52 of forming spring 50, and tapering section 41 of main body spring 30 are preferably bonded between approximately 0.5cm and

approximately 2cm, and optimally, 1.3cm from the distal free end of core wire 12.

The choice of materials of springs 30 and 50 is important, as well, in providing the desired flexibility and degree of radiopacity. Preferably, core wire 12, 112 is formed from a flexible material such as 304 stainless steel, MP35N or nitinol. The material chosen for forming spring 50, 150 is selected based on stiffness and yield stress capability at low strain values such that distal end region 10, 110 can be easily formed by bending forming spring 50, 150 into the desired shape. In accordance with the principles of the present invention, the material from which forming spring 50, 150 is formed is also radiopaque. Thus, the preferred material for forming spring 50, 150 is an alloy of tungsten. Gold or platinum alloys may alternatively be used. Thus, forming spring 50, 150 serves a dual function of providing a formable distal end to the guidewire and also a radiopaque element that permits visualization of the distal end of the guidewire. As a result, the increase in diameter of forming spring 50 over the diameter of prior art radiopaque forming springs provides a more readily viewable radiopaque element.

Because the material used in the forming spring 50, 150 is generally less flexible than the material used for main body spring 30, 130 the increased diameter of the forming spring 50, 150 over that of prior art forming springs provides a more flexible forming spring. Because such easily formable material is in a spring configuration, rather than in the form of a ribbon having a substantially rectangular cross-section as in the prior art, the forming element of the guidewire of the present invention may be steered axisymmetrically after forming. Accordingly, the guidewire of the present invention is provided with a stable rotational structure at its tip, and has virtually no whipping action or resistance to multiplane tortuousity steering. Moreover, the shape of distal end region 10, 110 may be formed into multiplane compound curves and into more shapes both through forming and reforming than possible with prior art forming ribbons.

While the foregoing description and drawings represent the preferred embodiments of the present invention, it will be understood that various additions, modifications and substitutions may be made without departing from the spirit and scope of the present invention as defined in the accompanying claims. In particular, it will be clear that the present invention may be embodied in other specific forms, structures, arrangements, proportions, and with other elements, materials, and

components, without departing from the spirit or essential characteristics thereof. One skilled in the art will appreciate that the invention may be used with many modifications of structure, arrangement, proportions, materials, and components and otherwise, used in the practice of the invention, which are particularly adapted to specific environments and operative requirements without departing from the principles of the present invention. The presently disclosed embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims, and not limited to the foregoing description.

WHAT IS CLAIMED IS

1. A guidewire having a flexible distal end region that permits axisymmetric steering and forming, said guidewire comprising:

a core wire having a main body and a flexible distal end at said flexible distal end region of said guidewire;

a flexible first coil coupled to said distal end of said core wire, said first coil having a proximal section with a first outer diameter and a distal section with a second outer diameter smaller than said first outer diameter; and

a flexible second coil coupled to said first coil and positioned substantially concentrically over said distal section of said first coil;

wherein said second coil is formed from a formable material capable of reaching a stress value above its yield point such that said second coil maintains a desired bend imparted thereto to thereby impart a bend to said distal end of said guidewire.

2. A guidewire as in claim 1, wherein said second coil has an outer diameter substantially equal to said first outer diameter of said first coil.

A guidewire as in claim 2, wherein:

said guidewire further comprises a tip having an outer diameter substantially equal to said first outer diameter of said first coil;

each of said first and second coils has a distal end; and

said distal ends of said first and second coils are coupled to said distal tip.

3. A guidewire as in claim 2, wherein said first outer diameter of said first coil is between approximately 0.0254cm and approximately 0.0351cm.

4. A guidewire as in claim 1, wherein said first coil further comprises a tapering section between said proximal section and said distal section.

5. A guidewire as in claim 5, wherein said first coil is coupled to said core wire at said tapering section of said first coil.

6. A guidewire as in claim 6, wherein said proximal section of said first coil has a proximal end coupled to said core wire.

7. A guidewire as in claim 7, wherein:

said distal end of said core wire is tapered and comprises a successive series of alternating tapers and barrel segments including a proximal taper adjacent said main body and a distal free end formed as a tapered tip;

said barrel segments have diameters successively decreasing distally along said guidewire;

said proximal end of said first coil is coupled to said proximal taper of said tapered distal end of said core wire; and

said tapering section of said first coil is coupled to said tapered tip of said core wire.

8. A guidewire as in claim 5, wherein:

said second coil has a proximal end; and

said proximal end of said second coil is coupled to said tapering section of said first coil.

9. A guidewire as in claim 9, wherein said proximal section of said first coil has a proximal end coupled to said core wire.

10. A guidewire as in claim 10, wherein said first coil is coupled to said core wire at said tapering section of said first coil.

11. A guidewire as in claim 11, wherein:

said guidewire comprises a distal tip;

each of said first and second coils has a distal end; and

said distal ends of said first and second coils are coupled to said distal tip.

12. A guidewire as in claim 9, wherein said tapered section of said

first coil and said proximal end of said second coil are coupled to said distal end of said core wire.

13. A guidewire as in claim 9, wherein:

said distal end of said core wire is tapered and comprises a successive series of alternating tapers and barrel segments including a proximal taper adjacent said main body and a tapered tip;

said barrel segments have diameters successively decreasing distally along said guidewire; and

said proximal end of said first coil is coupled to said proximal taper of said tapered distal end of said core wire.

14. A guidewire as in claim 14, wherein said tapering section of said first coil and said proximal end of said second coil are coupled to said tapered tip of said tapered distal end of core wire.

15. A guidewire as in claim 1, wherein said proximal section of said first coil has a first pitch and said distal section of said first coil has a second pitch different from said first pitch.

16. A guidewire as in claim 16, wherein said second pitch is greater than said first pitch.

17. A guidewire as in claim 17, wherein said first coil is a closed stack.

18. A guidewire as in claim 1, wherein said second coil has gaps between the coil windings of said second coil.

19. A guidewire as in claim 1, wherein said second coil is formed from a radiopaque material.

20. A guidewire as in claim 20, wherein said second coil is formed

from a material selected from the group consisting of tungsten, gold, and platinum.

21. A guidewire as in claim 1, wherein said first coil is formed from a material selected from the group consisting of stainless steel, an aluminum nickel alloy, and nitinol.

22. A guidewire as in claim 1, wherein:

said core wire further comprises a distal free end;

said second coil and said distal section of said first coil extend distally beyond said distal free end of said core wire;

said guidewire further comprises a distal tip; and

said guidewire further comprises a reinforcement element extending between said distal free end of said core wire and said distal of said guidewire.

23. A guidewire as in claim 23, wherein said reinforcement element has a substantially circular cross-section that permits axisymmetric steering of said distal end region of said guidewire.

24. A guidewire as in claim 23, wherein said reinforcement element comprises a flexible thread.

25. A guidewire as in claim 1, wherein:

said guidewire further comprises a distal tip;

said core wire further comprises a distal free end having a substantially round cross-section; and

said distal free end of said core wire extends to said distal tip of said guidewire.

26. A guidewire having a flexible distal end region that permits axisymmetric steering and forming, said guidewire comprising:

a core wire having a flexible distal end region at said flexible distal end region of said guidewire;

a flexible main body spring coupled to said distal end region of said core wire; and

a forming element formed from a formable material in the shape of a coil spring.

27. A guidewire as in claim 27, wherein said forming element is positioned substantially concentrically over said main body spring.

28. A guidewire as in claim 28, wherein:

said main body spring has a proximal section with a first outer diameter, a distal section with a second outer diameter, and a tapering section between said proximal and said distal sections; and

said forming element is positioned over said distal section of said main body spring.

29. A guidewire as in claim 29, wherein:

said forming element has a proximal end; and

said proximal end of said forming element is coupled to said tapering section of said main body spring.

30. A guidewire as in claim 29, wherein said forming element has an outer diameter substantially equal to said first outer diameter of said proximal section of said main body spring.

31. A guidewire as in claim the 27, wherein:

said distal end of said core wire is tapered and comprises a successive series of alternating tapers and barrel segments including a proximal taper adjacent said main body and a tapered tip;

said barrel segments have diameters successively decreasing distally along said guidewire; and

said proximal end of said main body spring is coupled to said proximal taper of said tapered distal end of said core wire.

32. A guidewire as in claim 32, wherein:

said forming element has a proximal end; and

said tapering section of said main body spring and said proximal end of said forming element are coupled to said tapered tip of said tapered distal end of core wire.

33. A guidewire as in claim 27, wherein said forming element is formed from a radiopaque material.

34. A guidewire as in claim 34, wherein said forming element is formed from a material selected from the group consisting of tungsten, gold, and platinum.

35. A guidewire as in claim 27, wherein said main body spring is formed from a material selected from the group consisting of stainless steel, an aluminum nickel alloy, and nitinol.

36. A guidewire as in claim 27, wherein said forming element has gaps between the coil windings of said forming element.

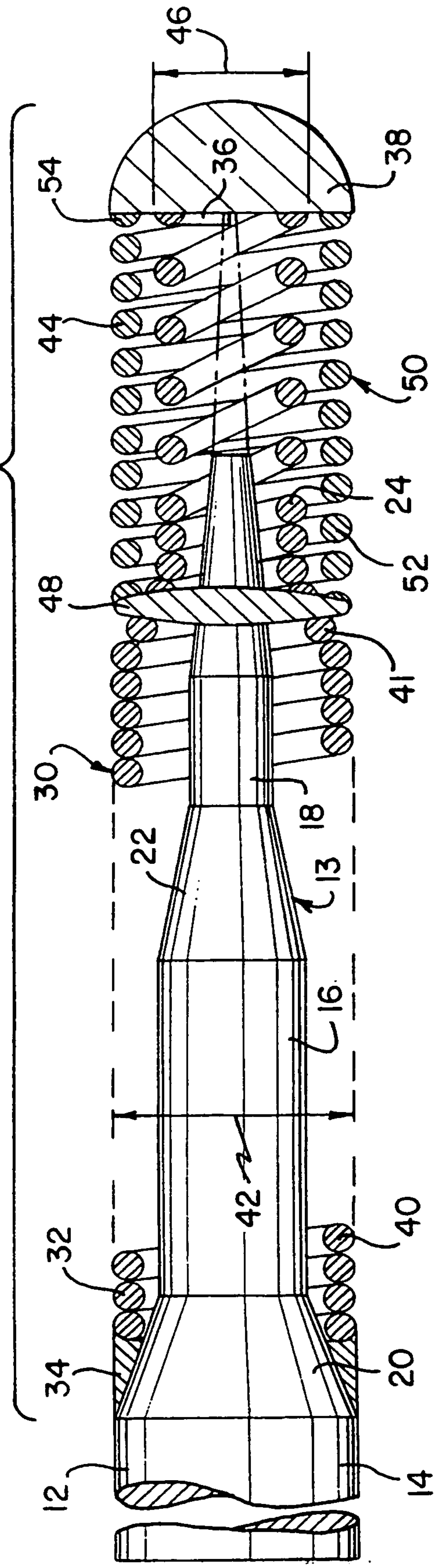

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FIG. 1

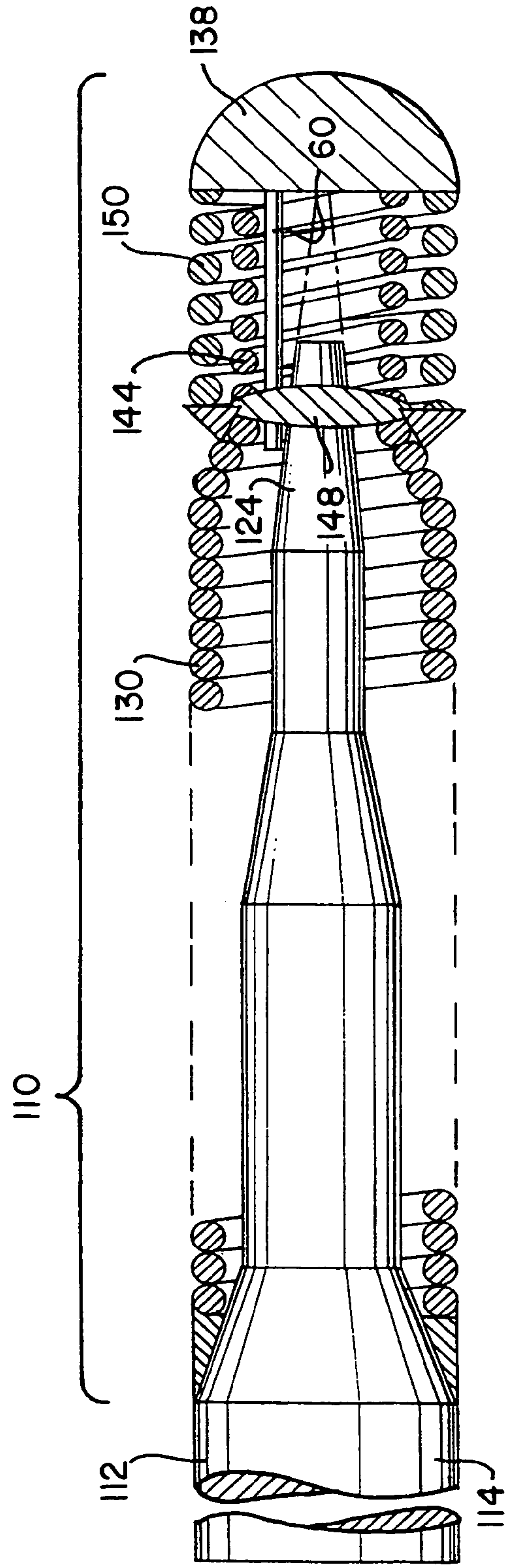

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FIG. 2

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/20168

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 551 444 A (FINLAYSON MAUREEN) 3 September 1996 see column 3, line 2 - line 31; figures ---	1
A	EP 0 729 765 A (SCHNEIDER EUROP AG) 4 September 1996 see column 5, line 19 - line 33; figure -----	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 February 1998	09/03/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Clarkson, P

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internatl. Application No
PCT/US 97/20168

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5551444 A	03-09-96	AU 5955896 A	18-12-96
		WO 9638195 A	05-12-96
EP 0729765 A	04-09-96	CA 2168309 A	03-09-96
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		US 5706826 A	13-01-98